

We claim:

1. A matrix material for a transdermal drug delivery device comprising a melt-blended mixture of a drug and a polyurethane polymer, said polymer having a process temperature of less than about 150 °C.
- 5 2. The matrix material of claim 1 wherein the polyurethane polymer has a process temperature of less than about 100 °C.
3. The matrix material of claim 1 wherein the polyurethane polymer  
10 has a process temperature of about 40 – 90 °C.
4. The matrix material of claim 1 wherein the polyurethane polymer is a polyether polyurethane.
- 15 5. The matrix material of claim 4 wherein the polyurethane comprises the reaction product of at least one aliphatic diisocyanate, at least one high molecular weight polyether polyol, and at least one low molecular weight glycol.
6. The matrix material of claim 5 wherein the diisocyanate comprises  
20 methylene bis(cyclohexyl) diisocyanate, the polyether alcohol is selected from the group consisting of poly tetramethylene glycol, poly propylene glycol, and polyethylene glycol.
7. The matrix material of claim 6 wherein the low molecular weight  
25 glycol is 1,4-butane diol.
8. The matrix of claim 1 wherein the matrix comprises a thickness of 1 – 12 mils (25.4 to 304.8 microns)

9. The matrix of claim 8 wherein the thickness is 2-6 mils (50.8 to 152.4 microns).

10. The matrix material of claim 1 wherein the polyurethane matrix  
5 comprises a room-temperature modulus between about 0.1 – 100 MPa.

11. The matrix material of claim 1 wherein the drug reservoir contains 0 - 20 wt% of at least one permeation enhancer.

10 12. A transdermal drug delivery device comprising:  
(a) a backing layer;  
(b) a drug reservoir on or adjacent the skin-proximal side of the backing layer, said drug reservoir comprising a melt-blended mixture of at least one drug and a polyurethane polymer, said polyurethane polymer having a  
15 process temperature of less than about 150 °C; and  
(c) means for maintaining the device in drug transmitting relationship with a body surface or membrane.

13. The device of claim 12 wherein said polyurethane polymer has a  
20 process temperature of less than about 100 °C.

14. The device of claim 12 wherein said polyurethane polymer has a process temperature of about 40 – 90 °C.

25 15. The device of claim 12 wherein said polyurethane polymer is a polyether polyurethane.

16. The device of claim 15 wherein the polyurethane comprises the reaction product of at least one aliphatic diisocyanate, at least one high molecular weight polyether polyol, and at least one low molecular weight glycol

5 17. The device of claim 16 wherein the diisocyanate comprises methylene bis(cyclohexyl) diisocyanate, the polyether polyol is selected from the group consisting of poly tetramethylene glycol, poly propylene glycol, and polyethylene glycol.

10 18. The device of claim 17 wherein the low molecular weight glycol is 1,4-butane diol.

15 19. The device of claim 17 wherein the polyether polyol is a mixture of at least two polymers selected from the group consisting of polytetramethylene ether glycol, polypropylene glycol, polyethylene glycol, and propylene glycol.

20. The device of claim 12 wherein the drug reservoir contains 0 - 20 wt% of at least one permeation enhancer.

20 21. The device of claim 20 wherein the permeation enhancer is selected from the group consisting of monoglycerides and lauryl pyroglutamate.

22. The device of claim 12 wherein the drug reservoir contains about 0.1 - 40 wt% of at least one drug.

25 23. The device of claim 22 wherein the drug is selected from the group consisting of fentanyl, oxybutynin, and fluoxetine.

24. The device of claim 12 wherein the drug reservoir contains 1 – 10 wt% fentanyl base.

25. The device of claim 24 wherein the drug reservoir contains 0 – 20 wt% of a permeation enhancer.

26. The device of claim 24 wherein the drug reservoir contains 2 – 15 wt% of a permeation enhancer.

27. The device of claim 12 wherein the drug reservoir contains 4 – 7 wt% fentanyl base, 4 – 13 wt% of a permeation enhancer, and 75 – 92 wt% of a polyether polyurethane.

28. The device of claim 27 wherein the permeation enhancer is selected from monoglycerides and lauryl pyroglutamate.

29. The device of claim 28 wherein the monoglyceride is glycerol monolaurate.

30. The device of claim 28 wherein the permeation enhancer comprises lauryl pyroglutamate.

31. The device of claim 27 wherein the means for maintaining the device in drug transmitting relationship with a body surface or membrane comprises an in-line contact adhesive on the skin-proximal surface of the drug reservoir.

32. The device of claim 31 wherein the adhesive comprises an acrylate adhesive.

33. The device of claim 12 wherein the mixture has a room-temperature modulus between about 0.1 – 100 MPa.

5 34. A method of making a reservoir matrix material for a transdermal drug delivery device comprising the steps of:

(a) providing at least one drug

(b) providing a polyurethane polymer having a process temperature less than about 150 °C;

10 (c) melt-mixing at least one of said drug into said polyurethane polymer at a temperature about equal to or less than the process temperature of the polyurethane polymer.

35. The method of claim of claim 34 wherein said polyurethane  
15 polymer has a process temperature of less than about 100 °C.

36. The method of claim 34 wherein said polyurethane polymer has a process temperature of about 40 – 90 °C.

20 37. The method of claim 34 wherein said polyurethane polymer is a polyether polyurethane.

38. The method of claim 37 wherein the polyurethane comprises the reaction product of at least one aliphatic diisocyanate, at least one high  
25 molecular weight polyether polyol, and at least one low molecular weight glycol

39. The method of claim 14 wherein the diisocyanate comprises methylene bis(cyclohexyl) diisocyanate, the polyether polyol is selected from the

group consisting of poly tetramethylene ether glycol, polypropylene glycol, and polyethylene glycol.

40. The method of claim 39 wherein the low molecular weight glycol is  
5 1,4-butane diol.

41. The method of claim 39 wherein the polyol is a mixture of at least  
two polymers selected from the group consisting of polytetramethylene ether  
glycol, polypropylene glycol, polyethylene glycol, and propylene glycol.

10

42. The method of claim 34 wherein the reservoir matrix further  
includes at least one permeation enhancer in such an amount that the matrix  
contains 0 - 20 wt% of permeation enhancer.

15

43. The method of claim 42 wherein the permeation enhancer is  
selected from the group consisting of monoglycerides and lauryl pyroglutamate.

44. The method of claim 34 wherein the matrix contains about 0.1 - 40  
wt% of at least one drug.

20

45. The method of claim 44 wherein the drug is selected from the  
group consisting of fentanyl, oxybutynin, and fluoxetine.

46. The method of claim 34 wherein the drug reservoir contains 1 - 10  
25 wt% fentanyl base.

47. The method of claim 46 wherein the drug reservoir contains 0 - 20  
wt% of a permeation enhancer.

48. The method of claim 46 wherein the drug reservoir contains 2 – 15 wt% of a permeation enhancer.

49. The method of claim 34 wherein the drug reservoir contains 4 – 7 wt% fentanyl base, 4 – 13 wt% of a permeation enhancer, and 75 – 92 wt% of a polyether polyurethane.

50. The method of claim 49 wherein the permeation enhancer is selected from monoglycerides and lauryl pyroglutamate.

51. The method of claim 50 wherein the monoglyceride comprises glycerol monolaurate.

52. The method of claim 49 wherein the permeation enhancer comprises lauryl pyroglutamate.

53. The method of claim 34 wherein the reservoir matrix has a room-temperature modulus between about 0.1 – 100 MPa.